

REMARKS

Claims 1-6, 8-15, and 19-43 are pending in this application. Claims 12, 14, 22-25, 27-38, 42, and 43 are withdrawn from consideration by the Examiner.

I. Rejection Under 35 U.S.C. §103

The Office Action rejects claims 1-6, 8-11, 13, 15, 19-21, 26, and 39-41 under 35 U.S.C. §103(a) as having been obvious over JP 2002-097116 to Hamada et al. ("Hamada") in view of U.S. Patent No. 5,639,785 to Kung ("Kung") and U.S. Patent No. 5,582,839 to McCarty ("McCarty"). Applicants respectfully traverse the rejection.

Claim 1 is directed to "[a] method of treating or reducing the likelihood of miniaturization of the hair follicle and/or alopecia, comprising administering to a human being an oral composition comprising at least one of taurine, hypotaurine, salts of taurine and salts of hypotaurine, and at least one polyphenol, in an amount effective for treating or reducing the likelihood of miniaturization of the hair follicle and/or alopecia." Claim 39 is directed to "[a] cosmetic process for treating or reducing the likelihood of miniaturization of the hair follicle and/or alopecia via the oral administration of an oral composition comprising taurine and/or hypotaurine and/or acceptable salts thereof, and at least one polyphenol."

Submitted herewith is a Declaration Under 37 C.F.R. §1.132 signed by the first named inventor, Albert Duranton, establishing that the methods of claims 1 and 39 are nonobvious. The experimental evidence described in the Declaration demonstrates that administering the combination of taurine and polyphenols yields unexpected results.

For reasons discussed below, an ordinarily skilled artisan would have immediately recognized that the experimental evidence set forth in the Declaration is of the type (e.g., nature and quality) that is relevant to methods of treating and reducing the likelihood of hair follicle miniaturization and/or alopecia, and would have understood (based on the evidence) that administering the combination of taurine and polyphenols produces a significant

synergistic effect, which is completely unexpected over the teachings of the applied references.

Taurine, polyphenols, and the combination of taurine and polyphenols were tested to determine their respective abilities to inhibit the amount of proline-rich proteins (namely collagen) that were synthesized and secreted by Normal Human Dermal Fibroblast ("NHDF") cells in which hyperproduction of proline-rich proteins was induced by Transforming Growth Factor β ("TGF- β "). See Declaration at page 2. Fibroblasts have the ability to synthesize collagen, which is a proline-rich protein. It is known in the art that inhibiting collagen metabolism is a mechanism for treating or reducing the likelihood of developing alopecia. See, e.g., specification at page 2, lines 16-23.

The experimental results described in the Declaration demonstrate that taurine (when administered without polyphenols) does not significantly inhibit the amount of proline-rich proteins synthesized and secreted by the fibroblasts. See page 7. The results further demonstrate that polyphenols (when administered without taurine) do not significantly inhibit the amount of proline-rich proteins synthesized and secreted by the fibroblasts unless administered at a concentration that has a cytotoxic effect on the fibroblasts. See pages 4-5 and 8.

Surprisingly, the combination of taurine and polyphenols significantly inhibited both newly synthesized proline-rich proteins and secreted proline-rich proteins. See pages 7-8. This effect was demonstrated when the polyphenols in the combination were administered at a concentration that was ten fold lower than the concentration of polyphenols administered alone that showed no significant inhibition, and at a concentration 100 fold lower than the concentration of polyphenols administered alone that had a cytotoxic effect.

Thus, the experimental evidence demonstrates that administering the combination of taurine and polyphenols has a significant synergistic effect. This synergistic effect is not

taught by the applied references and is completely unexpected over the teachings of the applied references.

For at least these reasons, the applied references would not have rendered obvious claims 1 and 39. Claims 2-6, 8-11, 13, 15, 19-21, and 26 depend from claim 1 and claims 40 and 41 depend from claim 39 and, thus, also would not have been rendered obvious by the applied references for at least the same reasons. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

II. Elected Species

As a species, Applicants elected methods involving the use of taurine in combination with polyphenols. See November 11, 2007 Preliminary Amendment and Response to Restriction Requirement. The Office Action indicates that claim 12, which depends from claim 1, has been withdrawn from consideration by the Examiner as being directed to a non-elected species. See page 3. Claims 14 and 22-25, which depend from claim 1 by way of intervening claim 12, were previously withdrawn from consideration by the Examiner.

However, claims 12, 14, and 22-25 read on the elected species and, thus, should be rejoined for examination. Claim 1 requires the step of "administering to a human being an oral composition comprising at least one of taurine, hypotaurine, salts of taurine and salts of hypotaurine, and at least one polyphenol." Thus, claim 1 reads on methods involving the use of taurine in combination with polyphenols--the elected species. Claims 12, 14, and 22-25 read on the elected species, regardless of the additional features they recite, because they also require this step by virtue of their dependency from claim 1. Accordingly, claims 12, 14, and 22-25 should be rejoined and fully examined for patentability because they are directed to the elected species.

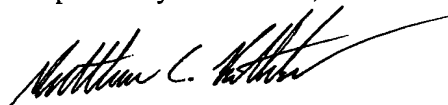
Rejoinder, examination, and allowance of claims 12, 14, and 22-25 are thus respectfully requested.

III. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of the application are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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Attachments:

Petition for Extension of Time
Request for Continued Examination
Declaration Under 37 C.F.R. §1.132
Information Disclosure Statement

Date: March 1, 2010

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